

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Pascal Drevet	Confirmation No.:	9114
Appl No.:	10/599,448	Group Art Unit:	1648
Filed:	03/08/2007	Examiner:	Stuart Snyder
For:	STABILIZED TAT ANTIGEN AND THE USE THEREOF FOR ANTI-HIV VACCINATION		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated October 8, 2008, in which the Examiner has required restriction between Group I, namely Claims 35-58; Group II, namely Claims 59; Group III, namely Claims 60; Group IV, namely Claim 61; Group V, namely Claim 62 and Group VI, namely Claims 63-66. Applicant hereby provisionally elects with traverse to prosecute the claims of Group I (Claims 35-58) and expressly reserves the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims.

With regard to the election of species, Applicant hereby elects Species a) The Tat sequence SEQ ID NO: 1 (Claim 45); and b) Pentosan polysulfate (Claim 37).

The invention relates to anti-HIV vaccine and in particular, to a new Tat-derived antigen which exhibits increased immunogenicity compared to the Tat antigens of the prior art. In the context of the present invention, it is worthwhile noting that an antigen refers to any substance that stimulates an immune response in the body (especially the production of antibodies).

The inventors have shown that a Tat antigen which is made resistant to proteolytic degradation (stabilized Tat) by formation of a complex with a ligand or by incorporation of hydrophobic groups, is at least 10 times more immunogenic than the existing Tat antigens (unmodified Tat and Tat toxoid). In addition, the stabilized Tat antigen exhibits an impaired transactivating activity indicating an absence of toxicity.

Therefore, the claims are directed to a vaccine composition comprising a stabilized Tat antigen (Claims 35-58), a method for preparing said stabilized Tat antigen (Claim 62) or the derived vaccine composition (Claim 59), a stabilized Tat antigen (Claims 60, 61) and derived polynucleotide, vector, cell (Claims 63-66).

The special technical feature common to the claimed invention is a **stabilized Tat antigen as anti-HIV vaccine**.

This special technical feature is novel and not obvious in view of Marasco et al., J. Immunological methods, 1999, 231, 223-238 for the following reasons:

Marasco et al. relates to anti-retroviral gene therapy for the treatment of HIV infection and AIDS. More precisely, Marasco et al. relates to the use of gene therapy through the introduction of anti-retroviral resistance genes into CD4+ T cells, to obtain a long term suppression of viral replication. Marasco et al. teaches that anti-Tat intracellular antibodies bind to Tat and inhibit viral genes transcription. Therefore, Marasco et al. discloses the use of anti-Tat intracellular antibodies as anti-retroviral gene therapy against HIV (Figure 1).

The anti-retroviral gene therapy strategy disclosed by Marasco et al. is different from the anti-HIV vaccine strategy of the invention which comprises the induction of an immune response (antibodies, CD4+ and CD8+ T cells) directed against Tat using a stabilized Tat antigen, for example a complex between Tat and its ligand (Tat/ligand).

Furthermore, contrary to the Examiner's opinion, as stated in the restriction requirement (item 2, page 2; item 4, page 4), Marasco et al. neither discloses or suggests that a complex between Tat and its ligand (Tat/ligand complex) is resistant to proteolytic degradation and more immunogenic than Tat. Therefore, the objection as regards unity of invention which was raised in the Office communication is based on a *post-facto* analysis of the invention.

For these reasons, the special technical feature common to the claimed invention is novel and not obvious in light of Marasco et al.

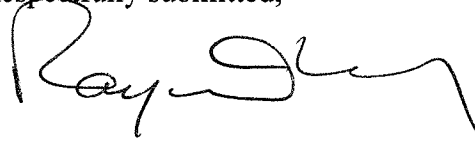
Therefore, the requirement of unity of invention is fulfilled since Groups I to VI relate to claims that are so linked as to form a single general inventive concept (PCT Rule 13.1 and Rule 13.2). Accordingly, reconsideration by the Examiner and withdrawal of the restriction requirement are respectfully solicited.

Appl No.: 10/599,448
Amdt. dated 11/07/2008
Reply to Restriction Requirement of October 8, 2008

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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